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| EXAMINER |
|---|
| LEE, YUN HAENG NMN |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3766 | |

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/764,429 | ZDEBLICK ET AL. | |
| | Examiner | Art Unit | |
| | Yun H. Lee | 3766 | |

*– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) *55-100* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 27-54* is/are rejected.

7)☒ Claim(s) *23-26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/30/04, 9/21/04, 11/15/04, 6/19/05, 1/30/06, 2/13/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, Claims 1-54 in the reply filed on 6/1/2006 is acknowledged. The traversal is on the ground(s) that it would not be unduly burdensome to perform a search on all of the claims together in the present application. This is not found persuasive because Inventions I and II are distinct for the reasons previously given and have acquired a separate status in the art as shown by their different classification. Hence, the searches would be different.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 55-100 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/1/2006.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. Examiner cannot find anywhere in the specification that discloses a shunt.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan et al. in view of Bennett et al. (US Pat. No. 5,213,098).

Regarding claim 1, Mulligan et al. disclose a method of enhancing cardiac pacing, the method comprising:

measuring at least one characteristic of a heart using one or more parameter measuring devices disposed in the heart (140, 142, 160, 170); and

calculating at least one cardiac performance parameter using the at least one measured characteristic (148, 162, 180).

dP/dt is one of the cardiac performance parameters calculated by Mulligan et al. (col. 16 line 53). Bennett et al. teach of using dP/dt as a cardiac performance parameter (col. 7 lines 15-54) for automatically adjusting at least one functional parameter of a cardiac pacing device such as a pulse duty cycle (col. 7 lines 55-60). This is advantageous since it allows the patient to enjoy the effects of PESP stimulation increased cardiac output (col. 7 line 61 – col. 8 line 5). Since Mulligan et al. employ PESP stimulation (col.

15 lines 55-62), it would have been obvious to one of ordinary skill in the art to automatically adjust at least one functional parameter of a cardiac pacing device such as a pulse duty cycle to allow the patient to enjoy the effects of PESP stimulation increased cardiac output.

Regarding claim 2, Bennett et al. teach of automatically adjusting a pulse duty cycle based on dP/dt (col. 7 lines 15-60).

Regarding claim 3-6, see Mulligan et al. col. 11 lines 12-15 and col. 12 lines 39-43.

Regarding claim 7, Mulligan et al. disclose a lead (32) comprising two or more electrodes (38, 40).

Regarding claim 8, see Mulligan et al. col. 11 lines 12-15 and col. 12 lines 39-43.

Regarding claim 9, Mulligan et al. disclose measuring pressure and volume (col. 16 lines 50-54).

Regarding claim 10, Mulligan et al. disclose measuring in a chamber of the heart (col. 15 lines 15-20).

Regarding claim 11, Bennett et al. also teach of measuring blood oxygen concentration for the cardiac performance parameter (col. 7 lines 28-32) in the same way that blood pressure is used. Thus, it would have been obvious to one of ordinary skill in the art to include blood oxygen sensors in any or all chambers of the heart for sensing blood oxygen concentration.

Regarding claim 16, Mulligan et al. disclose calculating dP/dt (col. 16 line 53).

Regarding claim 17, Mulligan et al. disclose pacing leads (16, 32, 52).

Regarding claims 18 and 19, Mulligan et al. disclose a lead (32) comprising two or more electrodes (38, 40) along its length.

Regarding claim 20, Bennett et al. teach of adjusting a pulse duty cycle (col. 7 lines 15-60).

Regarding claims 27-29, 31 and 32, Examiner takes Official Notice that it is old and well known in the art to have a display monitor for constantly displaying cardiac parameter data, retrieved from an implanted medical device and which can be requested by an external programmer command, in various forms including three-dimensional graphs. Thus, it would have been obvious to one of ordinary skill in the art to include the

limitations of claims 27-29, 31 and 32 in order to provide the user and physician with useful information.

Regarding claim 30, the measuring, calculating and adjusting steps discussed above are clearly meant to be done repetitively.

Regarding claim 33, Bennett et al. teach of setting the cardiac pacing device to fire with a timing such that it does not fire during each heart cycle (col. 7 lines 66-67).

Regarding claims 34 and 35, the limitations are a matter of obvious design choice. Examiner cannot find the criticality of these configurations in the disclosure.

Regarding claims 36-41, Mulligan et al. clearly disclose pace electrodes for stimulating more than one chamber. The automatically adjusting step discussed above will necessarily cause a first chamber to be stimulated and a stimulation of a second chamber will inherently follow. Since pacing occurs repetitively, there will necessarily be a pace to any first chamber that occurs before a pace to any second chamber.

Regarding claim 42, Bennett et al. teach of comparing at least one left ventricular end diastolic pressure (col. 18 lines 47-48) with a pre-defined control range (col. 17 lines 60-61) and adjusting the cardiac pacing device based on the comparison (col. 17 lines 61-63).

Regarding claim 43, Bennett et al. teach of comparing at least one right ventricular pressure (col. 18 lines 47-48) with a pre-defined control range (col. 17 lines 60-61) and adjusting the cardiac pacing device based on the comparison (col. 17 lines 61-63).

Regarding claim 44, when the pacing device stimulates the chambers of the heart, the valves are inherently stimulated due to conduction through the cardiac tissue.

Regarding claim 45, Mulligan et al. clearly discloses having leads in the right atrium, right ventricle and the coronary vein over the left ventricle, all of these leads having pressure sensors.

Regarding claims 47-52, the limitations have been met by the above discussions.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan et al. in view of Bennett et al. (US Pat. No. 5,213,098), further in view of Orth (US Pat. No. 5,423,323). As discussed above, Bennett et al. teach of measuring blood oxygen concentration as a cardiac performance parameter to be used in adjusting the cardiac pacing device. Orth teaches that systemic vascular resistance also gives a measure of the performance of the heart (col. 3 lines 13-15). Thus, it would have been obvious to one of ordinary skill in the art to further measure systemic vascular resistance as an additional cardiac performance parameter for adjusting the cardiac pacing device.

8. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan et al. (US Pat. No. 6,438,408) in view of Bennett et al. (US Pat. No. 5,213,098), further in view of Nappholz et al. (US Pat. No. 5,188,106). Nappholz et al. teach of assigning relative weights to various cardiac performance parameters (col. 27 lines 32-33) and determining an adjustment to be made to a functional parameter based on the cardiac performance parameters and relative weights (col. 27 lines 35-37). Thus, it would have been obvious to one of ordinary skill in the art to assign relative weights to a plurality of cardiac performance parameters and determine an adjustment to be made to a functional parameter based on the cardiac performance parameters and the relative weights.

9. Claims 46, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan et al. (US Pat. No. 6,438,408) in view of Bennett et al. (US Pat. No. 5,213,098), further in view of Meador et al. (US Pat. No. 6,234,973). Meador et al. teach of measuring an ambient pressure for use in calculating a gauge pressure (col. 4 lines 42-64). Meador et al. further teach that this is important because barometric pressure can have a negative effect on operating and detection functions of IMDs reliant on accurately sensing cardiac blood pressure changes that truly reflect a cardiac function or requirement for cardiac output (col. 3 lines 10-13). Thus, it would have been obvious to one of ordinary skill in the art to measure an ambient pressure for use in calculating a gauge pressure.

### *Allowable Subject Matter*

10. Claims 23-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766

yhl